

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

UNITED STATES OF AMERICA, <i>ex rel.</i>	§	
ELAINE GEORGE,	§	
	§	
Plaintiffs,	§	
	§	
V.	§	CIVIL ACTION NO. H-07-2467
	§	
BOSTON SCIENTIFIC CORPORATION	§	
and GUIDANT CORPORATION,	§	
	§	
Defendants.	§	

MEMORANDUM AND OPINION

In this *qui tam* action, the relator, Elaine George,¹ alleged that the defendants, Boston Scientific Corporation and Guidant Corporation, improperly promoted a medical device for an off-label use, causing physicians and hospitals to submit fraudulent reimbursement claims to Medicare and Medicaid. In her amended complaint, George asserted a violation of the False Claims Act (“Act”), 31 U.S.C. § 3729(a); retaliatory discharge under the Act, *id.* § 3730(h); and retaliatory discharge under Illinois law. (Docket Entry No. 58). This court granted the defendants’ motion to dismiss the amended complaint, but with leave to replead. (Docket Entry No. 81). George has filed a second amended complaint, alleging only retaliatory discharge under the Act. (Docket Entry No. 82, ¶¶ 44–48). The defendants again have moved to dismiss. (Docket Entry No. 87). George has responded, and the defendants have replied. (Docket Entry Nos. 90, 91).

¹This suit began before the relator married; her name then was Elaine Bennett.

Based on the pleadings; the motion, response, and reply; the record; and the applicable law, this court denies the defendants' motion to dismiss the second amended complaint. A scheduling and status conference is set for **April 16, 2012**, in Courtroom 11-B, at 5:00 p.m.

The reasons for this ruling are explained below.

I. Background²

A. The Parties

Guidant Corporation, headquartered in Indianapolis, designed, developed, and marketed cardiovascular medical products. The product at issue in this case is the FlexView Microwave Surgical Ablation System ("the FlexView device"). (Docket Entry No. 82, ¶ 6). Boston Scientific Corporation, headquartered in Massachusetts, also designs, develops, and markets medical products. In April 2006, Boston Scientific acquired Guidant's Cardiac Rhythm Management and Cardiac Surgery Units, which included the FlexView device. (*Id.*, ¶¶ 5–6).

In June 2006, during the transition from Guidant to Boston Scientific, Guidant hired Elaine George as a sales representative. (*Id.*, ¶ 4). George had over sixteen years of experience in the medical-device sales industry and had won awards for her sales work. (*Id.*, ¶ 26). George was hired as a territory manager for the Cardiac Surgery Division's Midwest region. She worked in central Illinois and throughout Missouri until she was fired in September 2006. (*Id.*, ¶ 4).

B. The FlexView Device

The FDA approves medical products for specific uses, which are identified in the product label. Using a product for other purposes is "off-label." The FDA generally prohibits manufacturers

²The factual allegations, which, if nonconclusory, this court must take as true for purpose of the motion to dismiss, come from George's second amended complaint. See *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 763 (5th Cir. 2011).

from marketing products for off-label uses. The FDA does not restrict hospitals from purchasing, or physicians from prescribing or using, products for off-label uses. To the contrary, off-label use of many medical devices and drugs is an accepted medical practice.³

The FDA approved the FlexView device for use in ablating—removing or destroying—soft tissue and striated, cardiac, and smooth muscle in surgical procedures. According to George’s complaints, the defendants trained their sales staff to promote off-label use of the FlexView device to treat atrial fibrillation, a condition in which the heart’s atria beats irregularly fast.

C. The Allegations on Retaliation

In July 2006, shortly after she began working for Guidant, George attended Boston Scientific’s Initial Training School in Santa Clara, California. (Docket Entry No. 82, ¶¶ 7, 28). At this training (and before, it appears), “George received extensive instructions regarding her responsibility to train doctors to use [the FlexView device] off-label to treat atrial fibrillation[.]” (*Id.*, ¶ 27). One day of training focused on regulatory restrictions on off-label promotion. George alleges that at a presentation for a number of employees,

Defendants’ compliance personnel discussed the dangers to the company associated with illegal off-label marketing. They described federal enforcement actions by the FDA and Department of Justice taken against competitors who had run afoul of the off-label marketing prohibition. They described how the government considered off-label marketing to be fraud and how other companies had incurred liability in the tens of millions of dollars as a result of their off-label marketing efforts. These presentations made it clear that off-label marketing was a type of fraud against the federal government that should be avoided at all costs.

³See generally, e.g., Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 FOOD & DRUG L.J. 653, 655–56 (2006).

(*Id.*, ¶ 29). One of the presenters, Charlie Merchant, a Boston Scientific sales trainer, specifically talked about off-label marketing restrictions in a way that led George to believe that the FlexView device could not be legally promoted for use in atrial fibrillation. “During the presentation, Ms. George asked for clarification as to whether there was any use for which BSC’s surgical ablation products could be promoted legally.” (*Id.*, ¶ 30). As soon as George asked her question, Merchant called for a ten-minute break to talk to George. Merchant “reprimanded” George and “warned that such questions could jeopardize her employment status.” (*Id.*) He told her to “stop asking questions regarding off-label marketing” of Boston Scientific’s surgical-ablation devices. (*Id.*)

In August 2006, George attended Boston Scientific’s national sales meeting in Beaver Creek, Colorado. At that meeting, Boston Scientific officially launched the FlexView device. A product manager announced that Boston Scientific “was close to obtaining FDA approval” to use the FlexView device in treating atrial fibrillation. (*Id.*, ¶ 31). The product manager stated that Boston Scientific “was in a ‘race’ against its competitors” to receive such approval. (*Id.*) George asked at that presentation whether promoting the FlexView device “would be viewed by the government as an illegal and prohibited off-label promotional activity” before the FDA issued its approval. (*Id.*, ¶ 31). At a break, George’s manager, Meg Zavich, followed her into the bathroom and

reprimanded Ms. George for challenging [Boston Scientific]’s marketing activities and for inquiring about prohibited off-label efforts. Ms. Zavich told her that if she harbored such concerns, she “might not be cut out for the job.” Ms. Zavich said she might have made a mistake in hiring Ms. George and suggested that Ms. George consider resigning her position.

(*Id.*, ¶ 32).

George alleged that during the following weeks, Zavich continuously criticized her. These criticisms led George to complain to Zavich that she was being held to a different standard and asked

to perform different functions than other new hires. (*Id.*, ¶ 33). George complained to Zavich that the “disparate treatment resulted from her challenging the company’s off-label promotional activities.” (*Id.*). Zavich did not deny that she treated George differently than the other new employees or George’s accusation about the reason. “She told Ms. George that it was her prerogative to hold Ms. George to different and higher standards and give her whatever assignments she wanted.” (*Id.*, ¶ 34). Zavich again suggested that George consider resigning. (*Id.*).

At the end of August 2006, before George had finished training, Zavich placed her on a Performance Improvement Plan for poor performance. George objected, without success, to the subjective nature of the plan’s goals. (*Id.*, ¶ 35). Zavich also required George “to reply within 30 minutes to every phone call or page from any account or [Boston Scientific] employee” or face job termination. (*Id.*, ¶ 36). During George’s remaining time at Boston Scientific, Zavich called her several times during the week, including twice in the middle of the night. (*Id.*).

George contacted Boston Scientific’s Human Resources Department for advice. Following the procedure set out in the Boston Scientific employee manual, George asked the Human Resources representative, “Camaya,” to help with her conflict with Zavich. Camaya refused, explaining that if George discussed the matter further, internally or externally, she would be fired immediately. Camaya suggested that George consider resigning. (*Id.*, ¶ 37). George alleges that two Boston Scientific senior sales representatives told her that Boston Scientific “was making her an example for the rest of the company” and “warned her that management was out to get her.” (*Id.*, ¶ 38).

On September 25, 2006, George was told to resign or face termination. On the same day, Merchant (the sales trainer) told another group at a training session “about Ms. George’s termination, saying that it should serve as a lesson to keep your mouth shut and do your job.” (*Id.*,

¶ 40). Boston Scientific sent George an e-mail three days later telling her that she was fired. (*Id.*) According to George, Boston Scientific gave false reasons for firing her. One reason was that she had not completed a report on time. George alleges that a supervisor had directed her to wait until Zavich could review the report before submitting it. A second reason was that George had submitted a weekly report late. George alleges that Zavich gave her permission to do so. The third reason was “[a]n incident involving [her] efforts to return ‘trunk stock’ to Charlie Merchant[.]” George alleges that her efforts did not deserve the criticism she received. (*Id.*, ¶ 39). George alleges that after she was fired, Boston Scientific executives had her “blacklisted” from other companies affiliated with the medical-device and healthcare industries. (*Id.*, ¶ 42). She also alleges that Zavich later retaliated against at least two other employees who questioned Boston Scientific’s off-label promotion of the FlexView device. (*Id.*, ¶ 41).

George filed this *qui tam* lawsuit on November 9, 2006. (Docket Entry No. 1). George amended her complaint on March 27, 2007 to add retaliation claims in violation of the False Claims Act, 31 U.S.C. § 3730(h), and Illinois public policy. (Docket Entry No. 7). This court granted the defendants’ motion to dismiss that complaint, but granted George leave to amend. (Docket Entry No. 81). George filed a second amended complaint, asserting only the False Claims Act retaliation claim. (Docket Entry No. 82). The defendants again have moved to dismiss. (Docket Entry No. 87). The question is whether George’s second amended complaint, with its additional factual allegations, sufficiently pleads a retaliation claim under the Act.

II. The Applicable Law

A complaint may be dismissed when the plaintiff fails “to state a claim upon which relief can be granted.” FED. R. CIV. P. 12(b)(6). In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007),

and *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949–50 (2009), the Supreme Court confirmed that Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires “a short and plain statement of the claim showing that the pleader is entitled to relief.” FED. R. CIV. P. 8(a)(2). A complaint must contain “enough facts to state a claim to relief that is plausible on its face” to withstand a Rule 12(b)(6) motion. *Iqbal*, 129 S. Ct. at 1949. “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* Facial plausibility “does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.” *Id.* (quoting *Twombly*, 550 U.S. at 555). Nor is facial plausibility “akin to a ‘probability requirement’”; rather, “it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 556). Facial plausibility requires “the plaintiff [to] plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 129 S. Ct. at 1949. “Where a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of entitlement to relief.’” *Id.* (quoting *Twombly*, 550 U.S. at 557).

III. The Statute of Limitations

The defendants first argue that George’s retaliation claim is time-barred. “[T]he most closely analogous state limitations period applies” to retaliation claims under the Act. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 411 (2005). The parties agree that this court must look to Texas law to determine what statute of limitations to apply. The parties disagree on what state’s law applies. (Docket Entry No. 87, at 11–12; Docket Entry No. 90,

at 19). The defendants argue that this court should apply Texas’s 90-day statute of limitations for state whistleblower claims because George “voluntarily chose to pursue this case in Texas; therefore, she should be bound by the law of the forum she selected.” (Docket Entry No. 91, at 10 n.8). George argues that this court must first apply Texas choice-of-law rules to determine which state has the “most significant relationship” to this dispute, and apply that state’s statute of limitations. (Docket Entry No. 90, at 19–20); *see also Casa Orlando Apartments, Ltd. v. Fed. Nat’l Mortg. Ass’n*, 624 F.3d 185, 190 (5th Cir. 2010). Under that analysis, according to George, Missouri law would apply, or, in the alternative, Illinois or Indiana law. Under the law of any of those states, George’s retaliation claim is timely. (Docket Entry No. 90, at 21–22).

The defendants have not responded to George’s argument that the Texas choice-of-law rules preclude applying the Texas statute of limitations. But even accepting the defendants’ argument—that Texas limitations applies—George’s claim is timely. The Fifth Circuit recently held that the governing Texas statute of limitations for a False Claims Act retaliation claim is not the 90-day Texas Whistleblower Act limitations period, as the defendants argue, but rather the two-year statute of limitations for personal injuries. *Riddle v. Dyncorp Int’l Inc.*, 666 F.3d 940, 943 (5th Cir. 2012). George filed her retaliation claim within 180 days after she was fired. Even assuming that Texas limitations applies, as the defendants urge, her claim is timely. If the limitations period for Missouri, Illinois, or Indiana applies, as George urges, her claim is timely. Either way, the statute of limitations is not a basis for dismissal.

IV. Retaliation

Under the False Claims Act’s antiretaliation provision,

Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that

employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

31 U.S.C. § 3730(h)(1). The elements of an FCA retaliation claim are that: “(1) the employee engaged in activity protected under the statute; (2) the employer knew that the employee engaged in protected activity; and (3) the employer discriminated against the employee because she engaged in protected activity.” *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 510 (S.D. Tex. 2003) (citing *Moore v. Cal. Inst. of Tech. Jet Propulsion Lab.*, 275 F.3d 838, 845 (9th Cir. 2002)), *aff’d*, 111 F. App’x 296 (5th Cir. 2004) (per curiam); accord *United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App’x 366, 371–72 (5th Cir. 2011) (per curiam). This court dismissed George’s False Claims Act retaliation claim in her amended complaint because it failed to “allege sufficient factual allegations” and instead provided mere “threadbare recitations of the elements of an FCA retaliation claim[.]” (Docket Entry No. 81, at 63). In her second amended complaint, George has added factual allegations in support of her claim. The defendants’ renewed motion to dismiss is based on the argument that these additional allegations, taken as true, still fail to state a valid retaliation claim. The arguments are analyzed below.

A. Does the Second Amended Complaint Sufficiently Plead that George Engaged in Protected Activity?

The defendants assert that the second amended complaint fails to allege that George engaged in protected activity “because she did not complain about Defendants defrauding the government or making false claims for federal funds, nor did she inform management of her intent to file a qui tam action.” (Docket Entry No. 87, at 9). The defendants contend that “merely questioning the

legality of marketing techniques does not qualify as a protected activity.” (*Id.*, at 8). George disagrees. (*See* Docket Entry No. 90, at 10 (“BSC personnel knew precisely what ‘off-label marketing’ means and that it creates a distinct possibility for *qui tam* litigation.”)).⁴

To engage in protected activity under the Act, an employee need not “have filed an FCA lawsuit or [] have developed a winning claim at the time of the alleged retaliation.” *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 236 (1st Cir. 2004) (citing *United States ex rel. Yesudian v. Howard Univ.*, 153 F.3d 731, 741 (D.C. Cir. 1998)); accord *Schuhardt v. Washington Univ.*, 390 F.3d 563, 567 (8th Cir. 2004). Instead, an employee’s actions must be aimed at matters that reasonably could lead to a viable claim under the Act. *See Harrington v. Aggregate Indus.–Ne. Region, Inc.*, 668 F.3d 25, 32 (1st Cir. 2012); *Mann v. Heckler & Koch Defense, Inc.*, 630 F.3d 338, 344 (4th Cir. 2010); *Hoyte v. Am. Nat’l Red Cross*, 518 F.3d 61, 66 (D.C. Cir. 2008);

⁴George asks this court to take judicial notice of “the then-existing legal climate” in which companies in the pharmaceutical and medical-device industries were under federal investigation for possible False Claims Act violations for their off-label-marketing techniques. (Docket Entry No. 90, at 12). The defendants respond that this court should not take judicial notice because “a reasonable dispute exists as to whether an allegation regarding off-label marketing is widely known to cause FCA liability[.]” (Docket Entry No. 91, at 6). This court need not take judicial notice of the widespread knowledge about off-label marketing giving rise to government investigation and potential False Claims Act liability because George made nonconclusory allegations in her second amended complaint that Boston Scientific was aware of such a risk and told its employees about it. (Docket Entry No. 82, ¶ 29). George alleged that Boston Scientific had told her and other trainees about

federal enforcement actions by the FDA and Department of Justice taken against competitors who had run afoul of the off-label marketing prohibition. . . . [and] how the government considered off-label marketing to be fraud and how other companies had incurred liability in the tens of millions of dollars as a result of their off-label marketing efforts.

(Docket Entry No. 82, ¶ 29).

Moreover, George’s argument is not that “off-label marketing . . . automatically implicate[s] FCA liability,” as the defendants describe it. (Docket Entry No. 91, at 5). Instead, George argues that it was widely known that the federal government was investigating pharmaceutical and medical-device companies for possible False Claims Act violations based on off-label-marketing activities. Again, the court need not rely on judicial notice, *see Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011), because George alleged Boston Scientific’s awareness of this risk of off-label marketing.

Schuhardt, 390 F.3d at 567; *Moore*, 275 F.3d at 845; *McKenzie v. Bellsouth Telecomms., Inc.*, 219 F.3d 508, 515–16 (6th Cir. 2000); *United States ex rel. Gray v. Lockheed Martin Corp.*, Civ. A. No. 05-4201, 2010 WL 672017, at *2 (E.D. La. Feb. 19, 2010); *Velazquez v. LandCoast Insulation, Inc.*, Civ. A. No. 06-0174, 2007 WL 902297, at *4 (W.D. La. Mar. 22, 2007); *United States ex rel. Dyson v. Amerigroup Tex., Inc.*, No. Civ. A. H-03-4223, 2005 WL 2467689, at *2 (S.D. Tex. Oct. 6, 2005). The employee’s actions must be aimed at matters demonstrating a “distinct possibility” of False Claims Act litigation. *See United States ex rel. Sanchez v. Lymphatx, Inc.*, 596 F.3d 1300, 1303–04 (11th Cir. 2010) (per curiam); *Fanslow v. Chicago Mfg. Ctr., Inc.*, 384 F.3d 469, 479 (7th Cir. 2004); *Dookeran v. Mercy Hosp. of Pittsburgh*, 281 F.3d 105, 108 (3d Cir. 2002); *United States ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 748 F. Supp. 2d 95, 104 (W.D. Tex. 2010). Whether the test is stated as the “reasonably could lead” standard or the “distinct possibility” standard, four circuits find the standard satisfied when “(1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government.” *Hoyte*, 518 F.3d at 71 (internal quotation marks omitted); *accord Schuhardt*, 390 F.3d at 567; *Fanslow*, 384 F.3d at 480; *Moore*, 275 F.3d at 845.

The Fifth Circuit recognizes internal complaints that “concern false or fraudulent claims for payment submitted to the government” as protected activity under the Act, but requires that the complaints raise concerns about fraud. *See Patton*, 418 F. App’x at 372 (citing *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 952 (5th Cir. 1994)). In *Patton*, an unpublished case, the plaintiff–employee had worked as a carpenter for Shaw Services, a construction company. He alleged that “he complained repeatedly to on-site Shaw supervisors and to off-site management about fraudulent construction mistakes” as well as “to state and federal authorities about Shaw’s

work[.]” *Id.* (internal quotation marks omitted). After Shaw fired him, the employee sued, alleging retaliation under the Act. The district court granted summary judgment for Shaw, and the Fifth Circuit affirmed. “Mere criticism of Shaw’s construction methods, without any suggestion that Patton was attempting to expose illegality or fraud within the meaning of the FCA, does not rise to the level of protected activity.” *Id.* (citing *United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 736 (4th Cir. 2010)). The employee’s only evidence that he had internally complained about fraud was his conclusory declaration, which was not enough to defeat summary judgment. His complaints made no reference to defrauding the government, but only to construction mistakes. *Id.*

The Seventh Circuit’s decision in *Fanslow* illustrates the type of internal complaint that was enough to defeat summary judgment. In that case, the plaintiff–employee allegedly learned that the nonprofit corporation he worked for was diverting resources into a for-profit “dot com” spin-off to help the nonprofit’s clients. The employee voiced his concerns that this defrauded the government to a federal official, then to three internal executives, and then to his direct supervisor. 384 F.3d at 474–77. A week later, that supervisor placed him on a “Performance Action Plan” that “contained impossible-to-attain goals and targets as a condition of continued employment” that the supervisor used “to discriminate against, harass, and ultimately terminate the targeted employee[.]” *Id.* at 477. The nonprofit fired him, claiming “ongoing performance issues” and the use of a curse word in a work discussion (although his supervisor often cursed when speaking with employees). *Id.* at 478. The Seventh Circuit reversed the district court’s grant of summary judgment for the nonprofit. In its opinion, the *Fanslow* court indicated that internal complaints were protected activity under the Act. *See id.* at 481–82; *see also Perius v. Abbott Labs.*, No. 07 C 1251, 2009 WL 1851151, at *9

(N.D. Ill. June 26, 2009) (explaining that in *Fanslow*, the Seventh Circuit “suggested, without deciding, that internal complaints could constitute protected activity under the FCA, noting that protecting only employees who lodge complaints directly to the government would be a disincentive to use an internal complaint mechanism, thereby rendering less effective corporate efforts to self-police”).

Cases in other circuits are consistent. In *Karvelas*, the First Circuit defined protected activity as “investigations, *inquiries*, testimonies or other activities that concern the employer’s knowing submission of false or fraudulent claims for payment to the government.” 360 F.3d at 237 (emphasis added) (citing *Yesudian*, 153 F.3d at 740). The Sixth Circuit in *McKenzie* took the same approach, making it clear that such “internal reporting of suspected fraud or false claims” must have “some nexus to the FCA to satisfy the ‘in furtherance prong’ of an FCA claim, by reasonably leading to a viable FCA action.” 219 F.3d at 517 (citing *Yesudian*, 153 F.3d at 740, and *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996)). In *Sanchez*, the Eleventh Circuit explained that it is protected activity if an employee puts “her employer on notice of possible False Claims Act litigation by making internal reports that alert the employer to fraudulent or illegal conduct.” 596 F.3d at 1304 (citing *McKenzie*, 219 F.3d at 516, and *Eberhardt v. Integrated Design & Constr., Inc.*, 167 F.3d 861, 868 (4th Cir. 1999)). “If an employee’s actions, as alleged in the complaint, are sufficient to support a reasonable conclusion that the employer could have feared being reported to the government for fraud or sued in a *qui tam* action by the employee, then the complaint states a claim for retaliatory discharge under § 3730(h).” *Id.*

Under these cases, the focus is on whether the internal complaint “allege[s] fraud on the government.” *McKenzie*, 219 F.3d at 516 (citing *Robertson*, 32 F.3d at 951 (5th Cir.), and *Hopper*,

91 F.3d at 1269). George alleged in her second amended complaint that, on two occasions, she asked in employee meetings whether the federal government would view Boston Scientific's marketing of the FlexView device for off-label uses as fraud on the government. The first occasion was after presentations in which Boston Scientific trainers instructed George and other employees on potential False Claims Act liability for "illegal off-label marketing" activity. George alleged that the presentations described "how the government considered off-label marketing to be fraud and how other companies had incurred liability in the tens of millions of dollars as a result of their off-label marketing efforts. These presentations made it clear that off-label marketing was a type of fraud against the federal government that should be avoided at all costs." The presentations discussed "the dangers to the company associated with illegal off-label marketing" and "federal enforcement actions by the FDA and Department of Justice taken against competitors [of Boston Scientific] who had run afoul of the off-label marketing prohibition." (Docket Entry No. 82, ¶ 29). George alleged that given these warnings, she was surprised to hear a sales presentation on using the FlexView device for the off-label purpose of treating atrial fibrillation, because it appeared that there was "no legal way" to market for this off-label use. George alleged that during the presentation, in front of the group, she asked whether the FlexView device "could be promoted legally" in the manner suggested by Merchant, Boston Scientific's sales trainer. (*Id.*, ¶ 30). By asking whether the FlexView device "could be promoted legally" for the off-label use presented by the sales trainer, immediately after the presentations discussing illegal marketing activity and federal enforcement actions against Boston Scientific competitors for prohibited off-label marketing, George "alert[ed] the employer to fraudulent or illegal conduct" in the form of off-label marketing. *Sanchez*, 596 F.3d at 1304.

The second occasion occurred at another Boston Scientific products presentation. After a products manager explained that the FlexView device might soon receive FDA approval for use in treating atrial fibrillation, George asked—again in front of numerous employees—whether the company’s current marketing of the product to treat atrial fibrillation, without FDA approval for such treatment, “would be viewed by the government as an illegal and prohibited off-label activity.” (Docket Entry No. 82, ¶ 31).

Through these questions, George did not directly say to Boston Scientific, “Your marketing of the FlexView device is fraudulent and unlawful.” When viewed in context, however, her questions “are sufficient to support a reasonable conclusion that [Boston Scientific] could have feared being reported to the government for fraud or sued in a *qui tam* action by [George]” or by other employees attending the presentations. *Sanchez*, 596 F.3d at 1304. George did more than merely criticize the way in which Boston Scientific instructed its sales representatives to market the FlexView device. In this respect, the allegations in George’s amended complaint are distinguishable from the employee’s summary-judgment evidence in *Patton*. *See* 418 F. App’x at 372. George asked about the legality of Boston Scientific’s off-label-marketing practices after she and others were told that the federal government viewed such practices as fraud against the government. George’s twice-repeated questions about the legality of Boston Scientific’s off-label marketing practices raised a “distinct possibility” that she, or other employees attending the presentation, might bring False Claims Act litigation against Boston Scientific for those practices. George alleged that both times, she was immediately reprimanded for questioning the legality of Boston Scientific’s off-label marketing and warned that her job could be at risk. George has plausibly alleged that her

actions were aimed at matters that reasonably could lead to False Claims Act litigation against Boston Scientific.

B. Does the Second Amended Complaint Sufficiently Plead that Boston Scientific Was On Notice that George Had Engaged in Protected Activity?

The employer must be on notice that the employee is investigating fraud. *See id.* (citing *Robertson*, 32 F.3d at 952). “Notice can be accomplished by expressly stating an intention to bring a *qui tam* suit, but it may also be accomplished by any action which a factfinder reasonably could conclude would put the employer on notice that litigation is a reasonable possibility.” *United States ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1262 (D.C. Cir. 2004) (internal alteration omitted) (quoting *Eberhardt*, 167 F.3d at 868). The employer need not know “that the employee has filed or is contemplating such an action.” *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 105 (D. Conn. 2006) (citing *Yesudian*, 153 F.3d at 742, and *Karvelas*, 360 F.3d at 238). Rather, the employer must know that the employee:

was engaged in protected activity—that is, investigation or other activity concerning potentially false or fraudulent claims that reasonably could lead to a FCA case. *Yesudian*, 153 F.3d at 742–43 (noting that “requiring a plaintiff to advise his employer that he has filed or is contemplating filing a *qui tam* complaint would contravene the *qui tam* section of the Act itself” and “frustrate . . . congressional concern[s]”). To require an express or even an implied threat of a *qui tam* action would impose an unrealistic requirement on employees—insisting that employees inform their employers of their intention to sue them on behalf of a “defrauded government” would eviscerate the FCA’s incentives to investigate fraudulent activities. *Mikes*, 889 F. Supp. at 753.

Id.

Courts have found this notice prong satisfied based on allegations that the employee complained directly to her supervisors. *See Harrington*, 668 F.3d at 32; *United States ex rel.*

Sarafoglou v. Weill Med. College of Cornell Univ., 451 F. Supp. 2d 613, 624–25 (S.D.N.Y. 2006). “Internal reporting has been held to constitute protected activity, but if an employee wants to impute knowledge to the employer for purposes of the second prong of the analysis, he must specifically tell the employer that he is concerned about possible fraud.” *Smith*, 415 F. Supp. 2d at 105 (citing *Yesudian*, 153 F.3d at 743–44). At the same time, no “magic words”—such as “illegal” or “unlawful”—are necessary to place the employer on notice of protected activity. *Fanslow*, 384 F.3d at 484.

In arguing that Boston Scientific lacked notice that George was engaged in protected activity, the defendants focus on the fact that George has not alleged who made the decision to fire her or whether that person knew about the questions George asked at the sales meetings. (*See* Docket Entry No. 87, at 10–11). But George did allege that Zavich—her manager and supervisor—did know about at least one of the occasions in which she questioned off-label marketing in a large sales meeting. George alleged that Zavich was present at the second sales meeting and heard George ask about the legality of off-label marketing. George alleged that at a break, shortly after she had asked her question, Zavich followed her into the restroom, reprimanded her for challenging Boston Scientific’s marketing activities, and suggested that if George had such concerns, Zavich might have made a mistake hiring her and that she should consider resigning. (*Id.*, ¶ 32). George alleged that in the following weeks, Zavich held her to higher standards than other similarly situated employees; criticized her unfairly; put her on a Performance Improvement Plan; harassed her with late-night and frequent calls; unnecessarily required her to return any call or page within 30 minutes, regardless of the hour; and suggested that she resign. (*Id.*, ¶¶ 32–36).

“To clear the low bar required to establish a *prima facie* case, the fact that high-level [] executives learned of the appellant’s whistleblowing several months before his firing suffices to show knowledge.” *Harrington*, 668 F.3d at 32. Under the circumstances George alleged—her repeated questions, at large company presentations and in front of her manager, about the legality of Boston Scientific’s off-label marketing activity following the company’s warning about the illegality of such activity—there is a plausible basis to infer that she was raising concerns that the off-label marketing practices were fraudulent. *See Williams*, 389 F.3d at 1262. George has adequately pleaded that the defendants were on notice of her protected activity when the alleged retaliation began.

C. Does the Second Amended Complaint Sufficiently Plead that Boston Scientific Retaliated against George for Engaging in Protected Activity?

The last element required to prove a False Claims Act retaliation claim is that the employer’s “retaliation was motivated by the protected activity.” *Shekoyan v. Sibley Int’l*, 409 F.3d 414, 422 (D.C. Cir. 2005); *see also Dyson*, 2005 WL 2467689, at *3 (“To sustain a retaliation claim beyond the summary judgment stage, a plaintiff must offer evidence that would support a reasonable trier of fact in concluding that the plaintiff was terminated, at least in part, because of her protected activity.” (citing *Brandon v. Anesthesia & Pain Mgmt. Assocs., Ltd.*, 277 F.3d 936, 944 (7th Cir. 2002); *Yesudian*, 153 F.3d at 376; and *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1056–57 (N.D. Ill. 1998))). “The showing necessary to demonstrate the causal-link part of the *prima facie* case is not onerous; the plaintiff merely has to prove that the protected activity and the negative employment action are not completely unrelated.” *Dyson*, 2005 WL 2467689, at *3 (quoting *Mann*

v. Olsten Certified Healthcare Corp., 49 F. Supp. 2d 1307, 1317 (M.D. Ala. 1999)) (internal quotation marks and alterations omitted).

The core of the defendants' argument is that George has not adequately alleged causation because Boston Scientific lacked notice that George had engaged in protected activity. (See Docket Entry No. 87, at 10–11); see also *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 729 (10th Cir. 2006) (“Such an allegation [that the defendants had been placed on notice] is necessary to establish that Sikkenga’s termination was ‘because of’ her protected activity.”); *Gray*, 2010 WL 672017, at *5 (“Where as here, employer is not aware of any investigation involving false claims when it terminates the employee, the employee can not prove this ‘causation’ element[.]”). Given the conclusion that George has sufficiently pleaded that Boston Scientific was on notice, this argument is unavailing.

The defendants cite *Strong v. University Healthcare System, L.L.C.*, 482 F.3d 802 (5th Cir. 2007), to support their argument that “[i]t is not enough for Relator to simply allege a temporal proximity in order to show that she was a victim of retaliation.” (Docket Entry No. 87, at 11). In *Strong*, the plaintiff–employee brought a Title VII retaliation suit against her employer. The employer moved for summary judgment. The district court granted the motion, and the Fifth Circuit affirmed. On appeal, the employee argued that “summary judgment is simply inappropriate in retaliation cases where the adverse employment decision follows closely on the heels of the plaintiff’s complaint of discrimination.” *Id.* at 807. The Fifth Circuit “affirmatively reject[ed] the notion that temporal proximity standing alone can be sufficient proof of but for causation.” *Id.* at 808. At the same time, however, the Fifth Circuit recognized that “temporal proximity alone, when very close, can in some instances establish a *prima facie* case of retaliation.” *Id.* (citing *Clark Cnty.*

Sch. Dist. v. Breeden, 532 U.S. 268, 273 (2001)). Unlike *Strong*, the present case does not involve evidentiary sufficiency on a motion for summary judgment but pleading sufficiency on a motion to dismiss, in which the issue is whether the allegations plausibly state a prima facie case of retaliation. *Strong* does not preclude the conclusion that George has stated a prima facie case. *See also Williams*, 389 F.3d at 1262 (“By claiming that his suspension and termination occurred just after he disclosed the NAVAIR conversation to his superior, Williams has satisfactorily alleged that his protected activity caused Martin-Baker’s retaliation.”).

The allegations in the challenged second amended pleading are that George first asked about the legality of the off-label marketing in July 2006, asked again in August, was immediately reprimanded on both occasions, and after the second occasion was advised to consider resigning and then subjected to retaliatory harassment and performance demands, culminating in her September firing. George has alleged additional evidence of causation besides temporal proximity. Among other things, George alleged that:

- both Merchant (the Boston Scientific sales trainer) and Zavich (George’s manager) verbally reprimanded her immediately following each of her inquiries, (Docket Entry No. 82, ¶¶ 30, 32);
- after the first inquiry, Merchant told her to stop inquiring into the legality of Boston Scientific’s off-label-marketing activities or risk losing her job, (*id.*, ¶ 30);
- after the second inquiry, Zavich told her that she should consider resigning, (*id.*, ¶ 32);
- Zavich admittedly held her to “different and higher standards” than other new sales representatives, (*id.*, ¶¶ 33–34);
- Zavich placed her on a Performance Improvement Plan, although her training remained incomplete, to ensure that her performance would be judged subjectively rather than objectively, (*id.*, ¶ 35);

- Zavich harassed her through repeated phone calls, including calls in the middle of the night, (*id.*, ¶ 36);
- a human-resources representative instructed her not to discuss her allegations with anyone, whether inside or outside Boston Scientific, or risk termination; and told her that she should consider resigning, (*id.*, ¶ 37);
- according to other employees, Boston Scientific was using her as “an example for the rest of the company,” (*id.*, ¶ 38); and
- she was the victim of “distorted” and “trump[ed] up charges” used as a pretext for termination, (*id.*, ¶ 39).

“The Fifth Circuit has held that ‘the combination of suspicious timing with other significant evidence of pretext[] can be sufficient to survive summary judgment’” on a retaliation claim. *Dyson*, 2005 WL 2467689, at *4 (quoting *Shackelford v. Deloitte & Touche, LLP*, 190 F.3d 398, 409 (5th Cir. 1999)); *see also Strong*, 482 F.3d at 808.⁵ George’s detailed allegations go well beyond temporal proximity. Given those allegations, in addition to the allegations of close temporal proximity, George has sufficiently pleaded that her inquiries and termination were “not completely unrelated.” *Dyson*, 2005 WL 2467689, at *3. George has adequately alleged causation.

V. Conclusion


⁵As the Fifth Circuit explained in *Strong*:

In addition, Strong has grossly mischaracterized our holding in *Shirley*. The plaintiff in *Shirley* proved causation not by relying solely on temporal proximity, but by also showing that she had no disciplinary history during her nine years of employment and quickly was fired for incidents for which no evidence existed. *See Shirley*, 970 F.2d at 43. And, importantly, her boss made disparaging comments about her EEOC complaint and “harassed [her] to death about it” before firing her. *Id.*

482 F.3d at 808.

The defendants' motion to dismiss the second amended complaint alleging retaliatory discharge under the False Claims Act, (Docket Entry No. 87), is denied. A scheduling and status conference is set for **April 16, 2012**, in Courtroom 11-B, at 5:00 p.m.

SIGNED on March 27, 2012, at Houston, Texas.



Lee H. Rosenthal
United States District Judge